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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,333	07/31/2000	Anand C. Burman	U 012799-1	5586

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/630,333

Applicant(s)

BURMAN ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 2004-8-24.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The finality of the previous Office Action is withdrawn due to a new ground rejection.

Status of the Claims

2. Claims 1-12 and 21-30 are pending.

Applicants' amendment filed August 9, 2004 is acknowledged. Applicants' response has been fully considered. Claims 13 and 31-40 have been cancelled.

Therefore, claims 1-12 and 21-30 are examined. A proposed Examiner's Amendment has been suggested to the Applicant (see Interview Summary), however, it has not been accepted.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 13 and 31-40, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's cancellation of the claim in the amendment filed August 9, 2004.
4. The previous rejection of claims 13 and 31-40, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's cancellation of the claim in the amendment filed August 9, 2004.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*,

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422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 3, 5, 6, 12, 21, 22, 24 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U. S. Patent 6,492,330. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 3, 5, 6, 12, 21, 22, 24 and 25 in the instant application discloses a peptide of X-D-Phe-Gln-R1-R2-Val-R3-His-R4-NH₂, where X can be deleted, R1 can be Trp, R2 can be Ala or Aib, R3 can be Aib or Gly, and R4 can be Leu or Ile, or a pharmaceutically acceptable salt thereof, and a composition comprising the peptide. This is obvious in view of claims 1 and 2 of the patent which disclose a peptide of D-Phe-Gln-Trp-Ala-Val-Aib-His-Leu-NH₂ (corresponding to SEQ ID NO:3 of the application) D-Phe-Gln-Trp-Aib-Val-Gly-His-Leu-NH₂ (corresponding to SEQ ID NO:4 of the application), D-Phe-Gln-Trp-Aib-Val-Gly-His-Ile-NH₂ (corresponding to SEQ ID NO:6 of the application), or D-Phe-Gln-Trp-Ala-Val-Aib-His-Ile-NH₂ (corresponding to SEQ ID NO:7 of the application), and a composition comprising the peptide. Both the claims of instant application and the claims of the patent are directed to the peptide of SEQ ID NO: 3, 4, 6 or 7 (the sequence identification number in the instant application) and a composition comprising the peptide. Thus, claims 1, 2, 3, 5, 6, 12, 21, 22, 24 and 25 in present application, and claims 1 and 2 of the patent are obvious variations of the peptide of D-Phe-Gln-R1-R2-Val-R3-His-R4-NH₂,

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where R1 is Trp, R2 is Ala or Aib, R3 is Aib or Gly, and R4 is Leu or Ile, and a composition comprising the peptide.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1-12 and 21-30 are indefinite because of the use of the term “or a hydrolyzable carboxy protecting group”. The cited term renders the claim indefinite, it is not clear what the term indicates since the peptide of the formula has the amide (CO-NH₂) at the C-terminus. Claims 2-12 and 21-30 are included in the rejection for being dependent of a rejected claim and not correcting the deficiency of the claim from which they depend.
7. Claim 12 is indefinite because of the use of the term “an effective amount”. The cited term renders the claim indefinite, it is not clear what effective amount of the peptide would do?

Conclusions

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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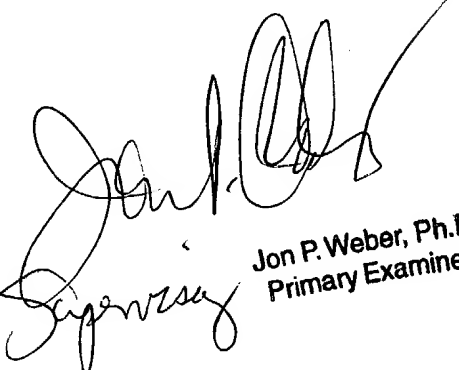
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

CMK
August 27, 2004


Jon P. Weber, Ph.D.
Primary Examiner